

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND )  
COMPOUNDING PHARMACY, INC. )  
PRODUCTS LIABILITY LITIGATION ) MDL No. 13-2419-RWZ  
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This Document Relates To: )  
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All Actions )  
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MEMORANDUM AND ORDER

[Docket Nos. 1775, 1810, 1823, 1824, 1826, 1836, 1838, 1854, 1879, 1945]

July 31, 2015

Boal, M.J.

Pending before the Court are a number of motions by parties and non-parties to this multi-district litigation regarding discovery sought by a number of the defendant clinics in this action. Individuals affiliated with New England Compounding Pharmacy, Inc. (“NECC”), many of whom have been indicted for conduct that overlaps with the conduct raised in these civil cases, seek a protective order precluding their depositions on the grounds that they intend to invoke their Fifth Amendment privilege against self-incrimination. Docket No. 1823. In part, as a result, NECC’s bankruptcy trustee and some NECC related entities seek orders precluding their Rule 30(b)(6) depositions on the grounds that there is no one who could testify on their behalf. Docket Nos. 1810, 1824, 1826, 1836, 1854, 1879. The U.S. Food and Drug Administration (“FDA”) seeks a protective order precluding its Rule 30(b)(6) deposition on the grounds that any such deposition would interfere with the criminal case against the NECC Insiders (defined below). See Docket Nos. 1775, 1838. For the following reasons, this Court rules as follows.

I. BACKGROUND

A. Introduction

This litigation involves claims for wrongful death and personal injury arising out of the administration of an injectable steroid, methylprednisolone acetate (“MPA”), manufactured by NECC. The complaints allege, in substance, that NECC produced contaminated MPA that led to serious fungal infections and, in some cases, death. Some plaintiffs have brought claims against numerous non-NECC parties, including the Tennessee Clinic Defendants,<sup>1</sup> the Saint Thomas Entities<sup>2</sup> and the Premier Defendants (collectively, the “Clinic Defendants”).<sup>3</sup>

B. NECC, The NECC Insiders And Related Entities

Gregory Conigliaro and Barry Cadden co-founded NECC in 1998. Master Complaint (Docket No. 545) at ¶ 29. NECC opened in the same Framingham, Massachusetts building that housed the Conigliaro family recycling plant and real estate businesses. Id.

Gregory Conigliaro provided financial advice to NECC. Id. at ¶ 33. Gregory Conigliaro’s sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both licensed pharmacists. Id. at ¶ 29. Barry Cadden held positions as the President, Chief Pharmacist, and

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<sup>1</sup> “Tennessee Clinic Defendants” refers to defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD.

<sup>2</sup> The “Saint Thomas Entities” refers to Saint Thomas Health, Saint Thomas Network, and Saint Thomas Hospital West f/k/a Saint Thomas Hospital.

<sup>3</sup> The “Premier Defendants” refer to Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC; Kimberley Yvette Smith, M.D., a/k/a Kimberley Yvette Smith-Martin, M.D.; Thomas Dwyer, M.D.; Richard C. DiVerniero, M.D.; John Catalano, M.D.; and Jeffrey Strauss, M.D.

Director of NECC. Id. at ¶ 32. Lisa Conigliaro Cadden was a board member and worked as a pharmacist at NECC. Id. at ¶ 33.

Gregory Conigliaro's brother, Dr. Douglas Conigliaro, was an anesthesiologist with a pain management practice in Florida. Id. at ¶ 30; Docket No. 1005 at 7. The Plaintiffs allege that Douglas Conigliaro was personally involved with NECC from its inception until it shut its doors. Master Complaint at ¶ 31. Because of legal troubles, however, he allegedly concealed his involvement. Id. Douglas Conigliaro's wife, Carla Conigliaro, initially owned 65% of NECC and was listed as NECC's President. Id.

The Conigliaros and Caddens opened another company in the same building, Medical Sales Management, Inc. ("MSM"). Id. at ¶ 35. MSM provided advertising and marketing services for NECC. Id.

In 2006, Gregory Conigliaro and Barry Cadden launched Ameridose, LLC ("Ameridose"), originally located in the same Framingham building as NECC. Id. at ¶ 37. Ameridose sold prefilled syringes and broke down large vats of liquid medications into smaller intravenous bags for individual treatments. Id.

Gregory Conigliaro also owned real estate companies GDC Holdings, Inc. and/or GDC Properties Management LLC ("GDC"), either or both of which owned the complex that housed NECC, Ameridose, and the family's recycling business. See id. at ¶ 25, 28.

### C. The Fungal Meningitis Outbreak

On September 24, 2012, the Tennessee Department of Health notified the Massachusetts Department of Public Health ("DPH") about a cluster of fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. Master Complaint at ¶ 61. These patients

had all received injections of preservative free MPA compounded at NECC. Id. As a result, the FDA and the DPH began investigating NECC. Id. at ¶¶ 63-69.

The DPH and FDA identified “serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public’s health and safety at risk.” Id. at ¶ 75. Among other things, the DPH found, based on its preliminary investigation, that:

- NECC did not follow industry standards for product sterilization;
- In violation of its state pharmacy license, NECC distributed large batches of compound “sterile” products directly to facilities for general use rather than requiring a prescription for an individual patient;
- NECC did not conduct patient-specific medication history or drug utilization reviews, as required by the regulations;
- The clean rooms used to compound drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing drugs to contamination;
- Powder hoods within the sterile compounding area were not thoroughly cleaned pursuant to industry standards or NECC’s standard operating procedures;
- “Tacky mats” used to trap dirt, dust and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris; and
- A leaky boiler next to the clean room, including a pool of standing water, created an environment susceptible to contaminant growth.

Id. at ¶¶ 76-86 and Ex. 1 (Docket No. 545-1). On October 3, 2012, NECC surrendered its pharmacy license and initiated a recall of MPA and other drug products prepared for injections in and around the spinal cord. Id. at ¶¶ 70-73.

On October 18, 2012, the FDA released definitive laboratory confirmation of the presence of fungal contaminants in sealed vials of MPA in a suspect lot prepared by NECC. Id. at ¶ 87.

The investigation eventually grew to cover other NECC-related entities and drugs. Id. at ¶¶ 101-118. The DPH asked Ameridose to shut down and Barry Cadden, Glenn Chin,<sup>4</sup> and Lisa Cadden's agreed to stop practicing as pharmacists. Id. at ¶ 101. The FDA also confirmed that other NECC products were contaminated. Id. at ¶¶ 102-103.

D. Congressional Investigation

After a congressional investigation, the U.S. House of Representatives Committee on Energy and Commerce issued a preliminary majority staff report titled “FDA’s Oversight of NECC and Ameridose: A History of Missed Opportunities?” Docket No. 1775-1. The report notes that, since 2004, the FDA had received numerous complaints about NECC and Ameridose calling into question the safety of the drugs the companies produced. See, e.g., Docket No. 1775-1 at 6.<sup>5</sup> The report concluded, among other things, that the FDA’s “inaction in the face of years of complaints and red flags associated with the safety of both companies’ products and underlying practices had a tragic ending. While nobody could have fully anticipated the scope of this terrible outbreak, FDA was on notice that something like this might occur.” Id. at 43.

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<sup>4</sup> Glenn Chin was a pharmacist at NECC. He was promoted to a supervisory pharmacist role in or around January 2010. The Plaintiffs allege that he was a “leader” at NECC. Master Complaint at ¶ 101.

<sup>5</sup> Citations are to the docket page numbers rather than the page numbers in the original documents.

E. The Criminal Investigation

In October 2012, the United States Attorney's Office for the District of Massachusetts ("USAO") began investigating NECC. Ortiz Aff. at ¶ 4.<sup>6</sup> The prosecution is led by a team of AUSAs in the USAO and attorneys from the Consumer Protection Branch of the Department of Justice ("DOJ"). *Id.* The investigation is being conducted by the U.S. Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI"); the FBI; the Department of Veterans Affairs, Office of the Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the United States Postal Inspection Service. *Id.*

In the course of the investigation, agents of FDA-OCI executed search warrants at NECC's Framingham facility. Ortiz Aff. at ¶ 6. As a result of the warrants, FDA-OCI agents seized more than 760,000 pages of documents; electronic media containing email, financial, and operational records; compounded drugs, packaged in vials; syringes, bottles, and bags; drug ingredients; lab materials; lab equipment; packaging materials; and surveillance videos. *Id.* As part of the criminal investigation, AUSAs and law enforcement agents conducted a thorough review of NECC's regulatory history, including its previous inspections by the FDA and the Massachusetts Board of Registration in Pharmacy, and NECC's representations about its business to regulators throughout its years of operation. *Id.* at ¶ 7.

On December 16, 2014, a federal grand jury sitting in Massachusetts returned a 131-count indictment with a variety of criminal charges against 14 owners, employees and associates of NECC. See United States v. Cadden, 14-cr-10363-RGS (D. Mass.). Barry Cadden and Glenn Chin were charged with racketeering, in violation of 18 U.S.C. § 1962, based in part on 25 acts of second degree murder in several states. Ortiz Aff. at ¶ 8. Cadden and Chin face a maximum

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<sup>6</sup> "Ortiz Aff." refers to the Declaration of United States Attorney Carmen M. Ortiz. Docket No. 1838-3.

sentence of life imprisonment. Id. The indictment also charges that Cadden, along with four other defendants, conspired to defraud the FDA by purporting to operate NECC as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions, rather than as a drug manufacturer distributing drugs in bulk to customers and subject to heightened FDA oversight. Id.

The 14 defendants in the criminal case were arraigned on December 17, 2014. Ortiz Aff. at ¶ 9. Since that date, the USAO has provided the defense with approximately 8.7 million pages of discovery. Id. A trial has been set for April 2016. The prosecution team is engaged in pretrial proceedings, including interviewing new witnesses, continuing to review and assess seized documents and evidence, preparing and producing discovery to the criminal defendants, and responding to filings in the criminal case. Id. The government anticipates calling multiple FDA witnesses at trial. Id.

#### F. The Bankruptcy Proceedings

On December 21, 2012, NECC filed a voluntary petition for relief pursuant to chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts. Moore Aff. at ¶ 3.<sup>7</sup> Paul D. Moore was subsequently appointed Trustee for the chapter 11 estate of NECC. Id. at ¶¶ 4-5. NECC had ceased operations four months prior to the Trustee's appointment. Id. at ¶ 9. All employees had resigned or had been terminated. Id. Prior to his appointment, Moore had no involvement with, or knowledge of, NECC or its operations. Id.

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<sup>7</sup> "Moore Aff." refers to the Declaration of Chapter 11 Trustee in Support of Motion of the Chapter 11 Trustee for a Protective Order Pursuant to Fed. R. Civ. P. 26(c) Precluding the Tennessee Clinic Defendants from Conducting a Deposition of New England Compounding Pharmacy, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6). Docket No. 1810-2.

As Trustee, Moore's goal was to marshal all of the assets of NECC's chapter 11 estate for eventual distribution to creditors under chapter 11 of the Bankruptcy Code. Id. at ¶ 10. On May 20, 2015, the Bankruptcy Court entered an order confirming the Third Amended Joint Chapter 11 Plan of NECC (the "Plan"). Docket No. 1890 at 1.

In broad strokes, the Plan provides, among other things, that the Trustee will fund a Tort Trust to distribute compensation to victims of the outbreak. The Tort Trust was funded by settlements with NECC, its affiliates, owners, and some of their insurance companies. See generally Docket No. 1574.

The effective date of the Plan was June 4, 2015. Docket No. 1951. On the effective date, the NECC Insurance Policies were deemed completely exhausted and all of the insurer's obligations under the Insurance Policies extinguished. Plan § 5.02(i). As a result, any defense costs incurred by Moore would have to be paid out of the assets of the Tort Trust established to pay victims of the outbreak. See Docket No. 1811 at 7.

#### G. Comparative Fault

In the Master Complaint, the Plaintiffs allege that the Clinic Defendants should have undertaken certain due diligence prior to purchasing and administering MPA from NECC. See, e.g., Master Complaint at ¶¶ 152-206. The Clinic Defendants have asserted a comparative fault defense against a number of parties and non-parties.

As to NECC and the Insider Defendants, the Clinic Defendants allege that NECC and the Insider Defendants share most, if not all, of the responsibility for the meningitis outbreak and the resulting deaths and injuries. Docket No. 1860 at 2; Docket No. 1865 at 2; Docket No. 1869 at 3-4.

With respect to Ameridose, the Saint Thomas Entities allege that Ameridose was negligent in its role as NECC's distribution center and in its participation in the design and management of the cleanrooms in which the contaminated MPA was later compounded. Docket No. 1943 at 3.

As to the FDA, the Clinic Defendants allege that the FDA (1) failed to take action against NECC after receiving numerous complaints, and (2) failed to at least warn the public about those complaints.

The discovery at issue here is related to the Clinic Defendants' comparative fault defenses. The Tennessee Clinic Defendants and Saint Thomas Entities argue that Tennessee law applies to cases originally filed in Tennessee while the Premier Defendants argue that New Jersey law applies to cases originally filed in New Jersey. See Docket Nos. 1926, 1927, 1942. Accordingly, they argue that Tennessee and New Jersey law allows for apportionment of fault by the jury as against the conduct of a settling defendant or other third party. See id.

The PSC argues for application of Massachusetts law, which does not provide a comparative fault defense similar to that of Tennessee or New Jersey. See Docket No. 2004. Ameridose joins in the PSC's arguments. Docket No. 2018. The Clinic Defendants argue that even if Massachusetts law applies, evidence that other parties' conduct was a superseding or intervening cause is relevant to the determination of proximate cause. Docket No. 1926 at 3, Docket No. 1927 at 2-3; Docket No. 1942 at 4. The District Court has set a briefing schedule for choice of law issues. Docket No. 1938. For purposes of these motions, the Court assumes, without deciding, that evidence of non-party fault is relevant to these cases.

H. The Motions

1. Motions Related To NECC, The Insider Defendants And Related Entities

The Clinic Defendants have noticed the depositions of Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro and Glenn Chin (collectively, the “Insider Defendants”). Except for Lisa Conigliaro Cadden, all of the Insider Defendants are also defendants in the parallel criminal proceeding. See United States v. Cadden et al., No. 14-10363-RGS (D. Mass.). The Insider Defendants have responded to requests for admissions, interrogatories, and document requests served by the Saint Thomas Entities and the Tennessee Clinic Defendants by invoking their Fifth Amendment privilege against self-incrimination to each substantive question. Docket No. 1823 at 2. They now move for an order quashing their deposition notices and prohibiting their depositions because they intend to decline to answer all substantive questions and invoke their Fifth Amendment privilege against self-incrimination. Docket No. 1823 at 2.

On April 17, 2015, the Tennessee Clinic Defendants served on the Trustee a subpoena seeking the Rule 30(b)(6) deposition of NECC on 31 topics. Docket No. 1810-1.<sup>8</sup> The Trustee moves for a protective order preventing this deposition. Docket No. 1810. The Trustee states that he has no personal knowledge of the Rule 30(b)(6) topics listed in the subpoena and that any knowledge he has is based on pleadings filed in this case and communications with his counsel.

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<sup>8</sup> The subpoena also directed NECC to produce certain categories of documents. The Trustee is not seeking to quash the subpoena duces tecum and is separately serving a response and objection. Docket No. 1810 at 1. At oral argument, the Trustee represented that in response to the subpoena, he had identified the documents in the repository that had previously been produced that were responsive to the requests. Docket No. 1918 at 26. He also conducted additional searches of documents and made a supplemental production. Id. In addition, he identified certain requests for which he had no additional responsive documents. Id. Finally, the Trustee objected to several of the requests. Id. The Tennessee Clinic Defendants have not raised any issues regarding the production of documents by the Trustee.

Moore Aff. at ¶ 15. As a result of the criminal proceedings, Cadden and the Conigliaros will not consent to testify on behalf of NECC in any civil proceeding. Id. at ¶ 13; see also Docket No. 1823. The Trustee asserts that NECC has no officers, directors, managing agents or others who have knowledge of the Rule 30(b)(6) topics and who will consent to testify on NECC's behalf. Moore Aff. at ¶ 16.

Several defendants have also noticed the deposition of GDC and its employee Steven Higgins. Mr. Higgins has expressed his intention to invoke his Fifth Amendment privilege against self-incrimination. Docket No. 1837 at 2. Because the Insider Defendants and Higgins intend to invoke their Fifth Amendment privilege at any deposition, GDC states that it has no witness that it can designate to testify on its behalf in response to the deposition notice. Docket No. 1826 at 2.

The Saint Thomas Entities noticed a Rule 30(b)(6) deposition of MSM. MSM does not currently employ anyone and is not conducting regular business activities. Docket No. 1854 at 2. It argues, therefore, that the only individuals who could theoretically be designated as corporate representatives for its deposition are the Insider Defendants, who will not accept such a designation. Id.

The Saint Thomas Entities seek to take Ameridose's Rule 30(b)(6) deposition. Ameridose has filed a motion for a protective order, arguing that all of the individuals that could be designated to testify on its behalf are defendants in the criminal proceeding and will not consent to testify. Docket No. 1879-1 at 2. The Saint Thomas Entities filed a cross-motion to compel. Docket No. 1945.

2. Motions Related To FDA Rule 30(b)(6) Testimony

On March 6, 2015, the Tennessee Clinic Defendants served a subpoena on the FDA, seeking documents and calling for the FDA to produce one or more persons pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure to testify about 18 topics.<sup>9</sup> Docket No. 1775-2. On April 4, 2015, the Tennessee Clinic Defendants moved for an order compelling the FDA to comply with the subpoena. Docket No. 1775. The Tennessee Clinic Defendants and the FDA have reached an agreement regarding the production of documents. Docket No. 1838-1 at 6; see also Docket No. 1918 at 14. However, the FDA argues that it should not be subject to a deposition during the pendency of the Cadden criminal case.<sup>10</sup> The FDA filed a motion for a protective order on May 11, 2015. Docket No. 1838.

II. ANALYSIS

A. The Fifth Amendment

The Fifth Amendment to the U.S. Constitution declares in pertinent part that “[n]o person . . . shall be compelled in any Criminal Case to be a witness against himself.” This privilege may be asserted in a civil proceeding. SEC v. Druffner, 517 F. Supp. 2d 502, 510 (D. Mass. 2007). While it is unconstitutional to draw a direct inference of guilt from silence, the Court, in a civil case, may draw adverse inferences from the failure of proof of the party invoking the Fifth Amendment. *Id.* (citing Baxter v. Palmigiano, 425 U.S. 308, 318 (1976)).

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<sup>9</sup> Among other things, the subpoena seeks deposition testimony on the following topics: (1) the FDA’s authority to investigate, inspect, regulate, and take action against NECC; (2) the FDA’s investigation, inspections, regulation, and actions related to NECC; (3) the FDA’s cooperation with the State of Massachusetts in investigating, inspecting and taking action against NECC; (4) the information known by the FDA about NECC and whether/how it was made public; and (5) the FDA’s investigation and inspection of, and action against NECC, following the meningitis outbreak. See Docket No. 1775-2 at 10-14.

<sup>10</sup> FDA asks for a protective order only until thirty days after completion of the criminal trial or the entry of guilty pleas by all defendants. Docket No. 1838-1 at 2.

“For the privilege to attach, the questions and answers need not be directly incriminating. If a reply to a seemingly innocuous question reasonably will tend to sculpt a rung in the ladder of evidence leading to prosecution, the privilege may be appropriately invoked.” *Id.* (citing Hoffman v. United States, 341 U.S. 479, 486 (1951); United States v. Johnson, 488 F.2d 1206, 1209 (1st Cir. 1973)). “In other words, testimony which might lead indirectly to evidence that then could be used in a future criminal prosecution is eligible for Fifth Amendment protection.” United States v. Castro, 129 F.3d 226, 230 (1st Cir. 1997) (citing Murphy v. Waterfront Comm’n, 378 U.S. 52, 79 (1964)).

Generally, the privilege against self-incrimination “cannot be invoked on a blanket basis.” Vazquez-Rijos v. Anhnag, 654 F.3d 122, 129 (1st Cir. 2011). Rather, it must be invoked in response to specific questions. *Id.*; see also SEC v. Spencer Pharm., Inc., No. 12-cv-12334, 2014 WL 4179914, at \*3 (D. Mass. Aug. 19, 2014); Shakman v. Democratic Org. of Cook Cnty., 920 F. Supp. 2d 881, 888 (N.D. Ill. 2013); Bryant v. Turney, No. 5:11-CV-00128-TBR, 2012 WL 4471594, at \*4 (W.D. Ky. Sept. 26, 2012). “This rule makes practical sense [because] [t]he trial court must be able to review whether the privilege was properly invoked.” Vazquez-Rijos, 654 F.3d at 129 (citation omitted).

However, some courts have allowed a blanket assertion of privilege in “unusual cases” where “there is a reasonable basis for believing a danger to the witness might exist in answering *any* relevant question.” United States v. Ortiz, 82 F.3d 1066, 1073 (D.C. Cir. 1996) (emphasis in original); see also United States v. Moore, 682 F.2d 853, 856 (9th Cir. 1982) (recognizing exception to general rule where “based on its knowledge of the case and of the testimony expected from the witness, (the trial court) can conclude that the witness could ‘legitimately refuse to answer essentially all relevant questions.’”).

B. The Court's Inherent Power To Stay Civil Actions  
During The Pendency Of Criminal Proceedings

Courts may issue protective orders when appropriate. Rule 26(c)(1) provides that “[a] party or any person from whom discovery is sought may move for a protective order in the court where the action is pending. . . . The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. . . .” Fed. R. Civ. P. 26(c)(1). Rule 26 “confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required.” Seattle Times Co. v. Rhinehart, 467 U.S. 20, 36 (1984). “As specified in [Rule] 26(c), however, a showing of good cause is required to justify any protective order.” Baker v. Liggett Group, Inc., 132 F.R.D. 123, 125 (D. Mass. 1990) (citing Anderson v. Cryovac, Inc., 805 F.2d 1, 7 (1st Cir. 1986)). The party seeking a protective order has the burden of demonstrating good cause. Cartel Asset Mgmt. v. Ocwen Fin. Corp., No. 01-cv-01644-REB-CBS, 2010 WL 502721, at \*10 (D. Colo. Feb. 8, 2010).

In addition, federal courts have the inherent discretionary authority to stay a civil action for prudential reasons. Microfinancial, Inc. v. Premier Holidays Intern., Inc., 385 F.3d 72, 77 (1st Cir. 2004). “The pendency of a parallel or related criminal action can constitute such a reason.” Id. Whether to stay a case is a highly nuanced decision involving competing interests. Id. at 78. The First Circuit has identified the following factors bearing on the court’s decision whether to stay proceedings:

- (i) the interests of the civil plaintiff in proceeding expeditiously with the civil litigation, including the avoidance of any prejudice to the plaintiff should a delay transpire; (ii) the hardship to the defendant, including the burden placed upon him should the cases go forward in tandem; (iii) the convenience of both the civil and criminal courts; (iv) the interests of third parties; [] (v) the public interest; (vi) the good faith of the litigants (or the absence of it); and (vii) the status of the cases.

Id. (internal citations omitted). When determining whether the pendency of a parallel criminal proceeding warrants the stay of a civil proceeding, some courts consider the similarity of the issues underlying the criminal and civil actions. See, e.g., Doe v. Sipper, 869 F. Supp. 2d 113, 116 (D.D.C. 2012); In re Adelphia Communications Sec. Litig., No. 02-1781, 2003 WL 22358819, at \*3 (E.D.Pa. May 13, 2003). Indeed, some courts consider the similarity of issues the most significant factor. See, e.g., Doe, 869 F. Supp. 2d at 116 (citing Walsh Sec., Inc. v. Cristo Prop. Mgmt., Ltd., 7 F. Supp. 2d 523, 527 (D.N.J. 1998)). Here, the civil and criminal cases directly overlap.

C. The Balancing Of The Interests Weighs Heavily Against Allowing The Depositions Of Defendants In The Criminal Case

The Court is persuaded that the depositions of the Insider Defendants who are defendants in the criminal case should not go forward at this time. It is true that Courts generally require witnesses to invoke the Fifth Amendment privilege in a question-by-question basis. However, courts have also stayed discovery in a civil case during the pendency of a criminal proceeding. See, e.g., Four In One Co., Inc. v. SK Foods, L.P., No. CIV S-08-3017 MCE EFB, 2010 WL 4718751, at \*5-7 (E.D. Cal. Nov. 12, 2010); In re Adelphia Comm. Sec. Litig., 2003 WL 22358819 at \*3-7; Bridgeport Harbour Place, I, LLC v. Ganim, 269 F. Supp. 2d 6, 12 (D. Conn. 2002). Fifth Amendment concerns are a significant factor in those decisions. See, e.g., Four In One Co., Inc., 2010 WL 4718751, at \*5; Bridgeport Harbour Place, 269 F. Supp. 2d at 1069-1070. Those concerns are particularly important when the subject matter of both cases overlaps to a significant degree. Bridgeport Harbour Place, 269 F. Supp. 2d at 9. Here, the defendants are not seeking a stay of the entire case, but just their depositions.

Given the significant overlap between the civil and criminal actions, any attempt by the Clinic Defendants to depose the defendants in the criminal case will necessarily implicate their

Fifth Amendment rights. Although the Clinic Defendants argue that there are areas of inquiry that the Insider Defendants could testify about without needing to invoke the Fifth Amendment, such as the organizational structure of NECC, chains of command, and daily operations, see Docket No. 1860 at 9, even such apparently innocuous topics could be fraught with peril for those defendants given the criminal allegations against them. For example, testimony about the chains of command and daily operations might “furnish a link in the chain of evidence” in demonstrating the Insider Defendants’ knowledge of and participation in the conduct giving rise to the criminal case. See Hoffman, 341 U.S. at 486. While under normal circumstances the Clinic Defendants would be entitled to take the requested depositions, here in light of all the relevant considerations, including the Insider Defendants’ production of written discovery responses invoking the privilege in a question-by-question basis, the factors favor the Insider Defendants. Accordingly, the Court grants the Insider Defendants’ motion to the extent that it bars the Clinic Defendants from taking the depositions of those Insider Defendants that are also defendants in the criminal case pending resolution of the criminal charges against them.

The Court does not bar the depositions of Lisa Conigliaro Cadden and Steven Higgins. The Court has no basis to doubt that Ms. Gonigliaro Cadden and Mr. Higgins may be entitled to invoke the Fifth Amendment privilege against self-incrimination during their depositions. See In re Katrina Canal, No. 05-4182, 2007 WL 1959003, at \*2 (E.D. La. June 28, 2007) (citations omitted) (“[I]f a party reasonably apprehends a risk of self-incrimination, he may claim a privilege though no criminal charges are pending against him, . . . even if the risk of prosecution is remote.”). However, as they have not been indicted in the criminal case, their request to bar their depositions altogether is weaker. See, e.g., Microfinancial, Inc., 385 F.3d at 79 (“[A]n unindicted defendant who argues that going forward with a civil proceeding will jeopardize his

Fifth Amendment rights usually presents a much less robust case for such extraordinary relief.”);

In re Worldcom, Inc. Securities Litig., No. 02 Civ. 3288(DLC), 2002 WL 31729501, at \*4

(S.D.N.Y. Dec. 5, 2002) (noting that courts in the Southern District of New York have generally refused to stay civil proceedings where the defendant has not been indicted but is under criminal investigation). Accordingly, the Court denies Lisa Conigliaro Cadden and Steven Higgins’ request for a protective order preventing their depositions. They may, of course, choose to exercise their Fifth Amendment rights in an appropriate manner, on a question-by-question basis.

D.     A Protective Order Precluding The Rule 30(b)(6)  
Deposition Of NECC Is Warranted Under The Circumstances

“A corporation does not enjoy the privilege against self-incrimination guaranteed by the Fifth Amendment, as the privilege is a personal privilege enjoyed by natural individuals.” Amato v. United States, 450 F.3d 46, 49 (1st Cir. 2006). See also State Farm Mutual Automobile Ins. Co. v. Graffman, No. 04-CV-2609, 2007 WL 4285378, at \*2 (E.D.N.Y. Dec. 1, 2007) (“A corporation, even one controlled by a single individual, has no Fifth Amendment right not to testify.”). The fact that individual employees or officers have invoked the Fifth Amendment is insufficient by itself to justify a stay of discovery with respect to their corporations. State Farm, 2007 WL 4285378, at \*2. Nevertheless, the Trustee argues that NECC should not be subjected to a Rule 30(b)(6) deposition because he has no personal knowledge of the topics in the Rule 30(b)(6) notice and NECC has no officers, directors, managing agents or others who have knowledge of the Rule 30(b)(6) topics who are not planning on invoking their Fifth Amendment privilege and who will consent to testify on NECC’s behalf. Docket No. 1811 at 4.<sup>11</sup> This Court finds that a protective order is warranted under the circumstances.

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<sup>11</sup> The Clinic Defendants have not challenged this latter assertion.

A few courts confronted with similar situations have compelled a corporation to designate a person to testify on its behalf, even if that means retaining a person not previously associated with the corporation so that person can answer the questions. See, e.g., Martinez v. Majestic Farms, No. 05-060833-CIV, 2008 WL 239164, at \*2 (S.D. Fla. Jan. 28, 2008); see also W.R. Grace & Co. v. N&M, Inc., No. 1:06mc602WJG, 2006 WL 3694595, at \*2 (S.D. Miss. Dec. 13, 2006) (“A corporation that is in existence but no longer actively doing business can be compelled to produce a witness for a Rule 30(b)(6) deposition.”). They have held that the retained corporate representative must be provided with sufficient knowledge as can be reasonably gleaned from corporate documents. Id. One court stated that “[t]he view that the duty to educate a person with no prior knowledge is ‘prejudicial’ to a corporation has not prevailed, and it appears now to be recognized that the Rule 30(b)(6) deponent must be woodshedded with information that was never known to the witness prior to deposition preparation.” Brunet v. Quizno’s Franchise Co. LLC, No. 07-cv-01717-PAB-KMT, 2008 WL 5378140, at \*2 (D. Colo. Dec. 23, 2008) (citations omitted).

Nevertheless, the Court finds that under the unique circumstances of this case, the Trustee should not have to designate a Rule 30(b)(6) designee to testify on behalf of NECC. The Court has been unable to find a case quite like this one, where not only most of the principals of the corporation have been indicted and have expressed an intention to invoke their Fifth Amendment rights but where the corporation has also filed for bankruptcy and is no longer operating. One of the Trustee’s main responsibilities in the bankruptcy case was to marshal the assets of NECC for distribution to creditors, including the victims of the outbreak. He has no apparent personal knowledge of any of the proposed subjects for examination. The former owners and principals of NECC are not available to help with the preparation of Rule 30(b)(6)

witness. See City of Chicago v. Reliable Truck Parts Co., Inc., 768 F. Supp. 642, 646 (N.D. Ill. 1991) (“[T]his court cannot compel the individual defendants who choose to remain silent to respond to inquiries by the 30(b)(6) deponent.”). Therefore, preparing a Rule 30(b)(6) witness would be an extraordinary undertaking. Every dollar spent by the Trustee and/or his counsel investigating the topics listed in the Rule 30(b)(6) notice and preparing a witness with no prior knowledge of those topics results in one less dollar available to the victims.

Moreover, the Clinic Defendants inability to take NECC’s deposition does not limit their ability to conduct discovery from NECC altogether. The Trustee has already made many documents available in response to the subpoena. Docket No. 1811 at 5. It also appears that the Plaintiffs are willing to stipulate that NECC distributed the product administered by the Clinic Defendants, thereby eliminating the need for some of the discovery they seek. *Id.* Admittedly, the Clinic Defendants will be unable to conduct the discovery they would under normal circumstances. However, in balancing all of the factors, the Court finds that the Trustee is entitled to a protective order. Accordingly, the Court grants the Trustee’s motion.

**E.      The Affiliated Entities Need Not Produce A  
Rule 30(b)(6) Corporate Representative**

Ameridose, MSM and GDC also assert that because the Insider Defendants and Higgins intend to invoke their Fifth Amendment privilege against self-incrimination, there is no knowledgeable person to attend a Rule 30(b)(6) deposition who could testify on their behalf without asserting the privilege.<sup>12</sup> Docket No. 1824 at 1; Docket No. 1826 at 1-2; Docket No. 1854 at 2; Docket No. 1879-1 at 3-5; Docket No. 2017 at 2-4. As set forth above, some courts have held that a corporation must designate a person to testify on its behalf, even if that means

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<sup>12</sup> The Clinic Defendants do not appear to challenge this assertion.

retaining a person not previously associated with the corporation so that person can answer the questions. See, e.g., Martinez, 2008 WL 239164, at \*2; see also W.R. Grace & Co., 2006 WL 3694595, at \*2. However, that approach presents a unique set of difficulties in this case.

First, the former principals and employees with knowledge have Fifth Amendment concerns so they will not consent to testify. In addition, they cannot be forced to help in the preparation of a corporate designee.<sup>13</sup> See Reliable Truck Parts Co., Inc., 768 F. Supp. at 646. Finally, because the Affiliated Entities have not operated for over two years, they appear to lack the financial ability to hire a consultant to review documents and educate himself or herself about the Rule 30(b)(6) topics. See, e.g., Docket No. 2017 at 3. Accordingly, the Court grants the Affiliated Entities motion for a protective order precluding their Rule 30(b)(6) deposition.<sup>14</sup>

#### F. Rule 30(b)(6) Deposition Of The FDA

The FDA argues that it should not be required to produce any witness for deposition until 30 days after the completion of the trial in the criminal case or the entry of guilty pleas by all

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<sup>13</sup> While the Court has allowed the depositions of Higgins and Lisa Conigliaro Cadden to go forward, they have asserted an intention to invoke their Fifth Amendment rights and therefore cannot be forced to help in any witness preparation.

<sup>14</sup> The Saint Thomas Entities have cross-moved to compel Ameridose to both designate a Rule 30(b)(6) witness and to produce documents. Docket No. 1945. The Saint Thomas Entities' motion does not include an analysis regarding the propriety of Ameridose's objections to each of the document requests. Ameridose generally argues that the requests seek irrelevant documents but also does not address each request separately. See Docket No. 1997 at 3-6 (citing to Docket No. 1879). Ameridose also states that the cost of processing and producing documents would exceed \$1,000,000 but provides no support for that estimate other than Mr. Moriarty's conclusory assertions to that effect. Docket No. 1879-2; Docket No. 1997 at 4. Without more information from the parties, the Court is unable to rule on the Saint Thomas Entities' motion as it relates to the production of documents. Because the Saint Thomas Entities bear the burden on a motion to compel, see Judson v. Midland Credit Mgmt., Inc., No. 13-11435-TSH, 2014 WL 3829082, at \*1 (D. Mass. Aug. 1, 2014), the Court denies the motion without prejudice to the extent it seeks the production of documents.

Defendants in that action. Docket No. 1838-1 at 14-20.<sup>15</sup> The Tennessee Clinic Defendants argue that the FDA has not met its burden of demonstrating the need for a stay of its deposition. Docket No. 1881. In making their arguments, both parties focus on the First Circuit's seven factor test set forth in Microfinancial. Microfinancial, Inc., 385 F.3d at 77. While that test is instructive, it is not entirely applicable here as the FDA is not seeking a stay of all civil proceedings pending resolution of the criminal case. In any event, the Court finds that a protective order precluding the FDA's deposition until resolution of the criminal case is appropriate under the circumstances.

A deposition of the FDA now would likely interfere with the criminal investigation. The deposition topics relate to some of the same conduct at issue in the criminal prosecution. Given the FDA's involvement in the investigation that followed the outbreak, any potential deposition would likely implicate, among other things, the investigatory steps taken by the FDA-OCI agents in the criminal case. See Ortiz Aff. at ¶ 16. The Court finds that this factor weighs heavily against allowing the Tennessee Clinic Defendants to take the FDA's deposition.

The Court realizes that precluding the FDA's deposition until resolution of the criminal case might mean that the Tennessee Clinic Defendants will be unable to take the deposition of the FDA prior to the conclusion of common fact discovery in these cases. However, the Court's order does not limit the Tennessee Clinic Defendants' ability to obtain document discovery from the FDA. The Court understands that the FDA has already made a number of documents available to them and represented that the production should be complete by the end of July.

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<sup>15</sup> The FDA initially objected to the subpoena on numerous other grounds. Docket No. 1775-3. In response, in its motion to compel, the Tennessee Clinic Defendants addressed those objections. Docket No. 1775. The FDA is, however, not pressing those arguments before the Court and therefore they have not been addressed herein.

Docket No. 1918 at 15. To the extent that they have not already done so, the FDA must complete its document production within two weeks of the date of this order.

III. ORDER

For the foregoing reasons, the Court orders as follows:

1. The Tennessee Clinic Defendants' Motion to Compel Compliance with Subpoena to the United States Food and Drug Administration (Docket No. 1775) is granted in part and denied in part;
2. The FDA's Motion for a Protective Order (Docket No. 1838) is granted;
3. The Trustee's Motion for a Protective Order Precluding the Tennessee Clinic Defendants from Conducting a Deposition of NECC (Docket No. 1810) is granted;
4. The Insider Defendants' Motion for a Protective Order (Docket No. 1823) is granted in part and denied in part;
5. Ameridose's Motion for Joinder (Docket No. 1824) is granted;
6. MSM's Motion for Joinder (Docket No. 1854) is granted;
7. Steven Higgins' Motion for Protective Order and Motion to Quash or Modify Subpoena (Docket No. 1836) is denied;
8. Ameridose's Motion for a Protective Order (Docket No. 1879) is granted; and
9. Saint Thomas Entities' Cross-Motion to Compel (Docket No. 1945) is denied as to Ameridose's deposition and denied without prejudice with respect to the production of documents.

/s/ Jennifer C. Boal  
JENNIFER C. BOAL  
United States Magistrate Judge